Air License Minor Revision Application

Sterilization Unit Installation and Generator Opacity Limit Modification

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800-426-4262

0214584.21
The Jackson Laboratory
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TABLE OF CONTENTS

TABLES

APPENDICES

1. PROPOSED LICENSE AMENDMENT

1.1 INTRODUCTION

The Jackson Laboratory (JAX), located at 600 Main Street, Bar Harbor, Maine, is an independent non-profit biomedical research institution whose mission is to improve the quality of human life through discoveries arising from JAX's genetic research and by enabling the research and education of others. JAX is the world's largest mammalian genetic research facility that also serves the global scientific community as the key provider of critical genetic resources. Each year, JAX supplies universities, medical schools, and research laboratories all over the world with approximately 2 million JAX®Mice from more than 4,000 varieties, 97% of which are available only from JAX. JAX employs approximately 1,300 permanent and 100 part time personnel.

JAX is currently a minor source of air emissions that operates under Maine Department of Environmental Protection (Maine DEP) Air Emission License No. A-93-71-X-R issued on November 24, 2014 and subsequently amendment by License Nos. A-93-71-Y-A, A-93-71-Z-A, A-93-71-AA-A, and A-93-71-BB-A. The air licenses permit JAX to operate boilers, generators, incinerators, and sterilization units in support of the Bar Harbor facility.

JAX is proposing to install a new 3M Steri-Vac GS8X ethylene oxide (EtO) sterilizer and associated abator in Building 74. In addition, JAX is proposing to revise the current opacity limits for the generators, including units Generator #2, #3, #6, #8, #9, and #10. Woodard & Curran has prepared this application on behalf of JAX to amend the current license to permit these modifications. The proposed modifications will constitute a minor revision under Maine DEP Chapter 115 regulation as calculated project emissions do not exceed the minor revision emission thresholds. A summary of the potential emissions from the proposed modification is summarized below in **Table 1-1**.

Table 1-1: Proposed New Sterilizer Potential Emissions

Pollutant	Proposed Sterilizer PTE [TPY]	Minor Revision Threshold [TPY]	Project Classification [Major/Minor/Revision]
VOC/HAP	0.002	4	Revision
Total	0.002	8	Revision

1.2 APPLICATION CONTENTS

A summary of the proposed equipment and associated pollution control equipment is provided in **Section 1.3**. **Section 2** contains a review of Federal air regulations as they apply to the proposed equipment and **Section 3** contains the required air pollution control technology analysis, including a Best Available Control Technology (BACT) review. **Section 4** contains a summary of the proposed opacity alternative work practice standards for the generator units.

Appendix A contains the EtO sterilizer emission calculations. **Appendix B** contains manufacturer's literature for the proposed equipment. A Safety Data Sheet (SDS) for the EtO cartridges is provided in **Appendix C**. The Chapter 115 signatory sheet signed by the responsible official is included in **Appendix D**.

1.3 PROPOSED PROJECT DESCRIPTION

JAX is proposing to install a 3M™ Steri-Vac GS8X dual cycle ethylene oxide (EtO) gas sterilization unit with a chamber capacity of 7.9 cubic feet. The Steri-Vac system uses sealed EtO cartridges that are only punctured once the cartridge is inside the locked, negative pressure sterilization chamber, minimizing the potential for EtO leaks. The EtO cartridges are single-use and contain 170 grams of EtO (0.37 pounds) each. A safety data sheet for the EtO cartridges is provided in **Appendix C**. Emissions of EtO from the sterilization units are control by an abator. The 3M™ EtO Abator Model 50 converts the EtO exhausted from the sterilization unit into carbon dioxide (CO_2) and water vapor. The Model 50 Abator is capable of achieving an EtO destruction efficiency of 99.9%. Specification sheets for the Steri-Vac GS8X sterilization units and the EtO Abator Model 50 are provided in **Appendix B**.

2. REGULATORY REVIEW

2.1 FEDERAL AIR REGULATIONS

The proposed EtO sterilization unit is potentially regulated by two Federal Environmental Protection Agency (EPA) National Emission Standards for Hazardous Air Pollutants (NESHAP) regulations. The applicability of each regulation is summarized below.

40 CFR Subpart 63 WWWWW—National Emission Standards for Hospital Ethylene Oxide Sterilizers

Hospitals that are area sources of hazardous air pollutants (HAPs) are subject to Subpart WWWWW - National Emission Standards for Hospital Ethylene Oxide Sterilizers. Hospitals are defined in Subpart WWWWW as facilities that provide medical care and treatment for patients under supervision of licensed physicians and under nursing care. JAX does not provide any treatment, thus it does not meet the definition of a hospital and is not subject to this subpart.

40 CFR Part 63 Subpart O—Ethylene Oxide Emissions Standards for Sterilization Facilities

All sterilization facilities that use 1 ton or more of ethylene oxide during any consecutive 12-month period in sterilization or fumigation operations are subject to Subpart O—Ethylene Oxide Emissions Standards for Sterilization Facilities. JAX is exempt from this regulation, pursuant to 40 CFR §63.360(d), as it is a research or laboratory facility as defined in Section 112(c)(7) of the Clean Air Act Amendment of 1990.

3. AIR POLLUTION CONTROL ANALYSIS

3.1 OVERVIEW

The addition of the ethylene oxide sterilization operation at JAX represents a minor revision under Maine DEP Chapter 115 regulations, thus JAX must demonstrate that the emissions from each constructed, reconstructed, or modified emissions unit will receive BACT as defined in Maine DEP Chapter 100 regulations. See Maine DEP Regulation Chapter 115 § 4(A)(4)(d). BACT is defined as:

> An emission limitation (including a visible emissions standard) based on the maximum degree of reduction for each pollutant emitted from or which results from the new or modified emissions unit which the Department on a case by case basis, taking into account energy, environmental and economic impacts and other costs, determines is achievable for such emissions unit through application of production processes or available methods, systems, and techniques, including fuel cleaning or treatment or innovative fuel combination techniques for control of each pollutant. In no event shall application of BACT result in emissions of any pollutant which would exceed the emissions allowed by any applicable standard under 40 CFR Part 60 and 61 or any applicable emission standard established by the Department. If the Department determines that technological or economic limitations on the application of measurement methodology to a particular emissions unit would make the imposition of an emission standard infeasible, a design, equipment, work practice, operational standard or combination thereof may be prescribed instead to satisfy the requirement for the application of BACT. Such standard shall, to the degree possible, set forth the emission reduction achievable by implementation of such design, equipment, work practice or operation, and shall provide for compliance by means which achieve equivalent results. (Maine DEP Regulation Chapter 100 § 18)

The proposed 3M™ Steri-Vac GS8X dual cycle gas sterilization unit emits ethylene oxide (EtO) which is both a volatile organic compound (VOC) and hazardous air pollutant (HAP). The following BACT analysis for VOCs and HAPs has been prepared in accordance with the Northeast States for Coordinated Air Use Management (NESCAUM) BACT Guideline. There are five key steps in the BACT Procedure:

1. Identify all control technologies applicable to the process;
2. Eliminate technically infeasible options;
3. Rank remaining control technologies by control effectiveness;
4. Evaluate technically feasible control alternatives (energy, environmental, and economic impacts) if a control technology less effective than the top option is proposed as BACT; and
5. Select BACT in consideration of energy, environmental, and economic impacts.

3.2 CONTROL OF VOC AND HAP

EtO emissions from sterilization units can be feasibly controlled using add-on pollution control equipment such as wet scrubbers, catalytic oxidizers, or condensers. All three types of pollution control equipment can achieve control efficiencies greater than 99%. Wet scrubbers produce a wastewater effluent that requires disposal and/or treatment, making this pollution control option environmentally infeasible. A condenser would also produce a by-product ethylene oxide stream that would require disposal and treatment, making this pollution control option also environmentally infeasible.

JAX is proposing to install a catalytic oxidizer abator as BACT for control of EtO emissions from the sterilization unit. The catalytic oxidizer will control EtO emissions by +99%, resulting in an EtO emission rate of 0.004 lbs/batch. At continuous operation with a catalytic oxidizer, the sterilization unit could potentially emit 3.3 pounds per year of EtO.

4. ALTERNATIVE GENERATOR OPACITY LIMIT

Currently, the generator units, Generator #2, #3, #6, #8, #9, and #10, are subject to a visible emission limit of 20% opacity on a six-minute block average basis per 06-096 CMR Chapter 101 Section 2(B)(1)(d). As an alternative to the opacity limitation during startup and shutdown periods, JAX is proposing to meet work practice standards as Best Practical Treatment (BPT). These units' proposed new opacity limits would be 20% on a six-minute block average basis except for periods of startup and shutdown, not to exceed 30 minutes. For periods of startup and shutdown, the generators would be subject to the following work practice standards:

(1) The unit operator shall maintain a log (written or electronic) of the date, time, and duration of all unit startups which result in the operator electing to comply with this Section.

(2) The unit shall be operated in accordance with the manufacturer's emission-related operating instructions.

(3) The unit operator shall minimize the engine's time spent at idle and minimize the engine's startup time to a period needed for appropriate and safe loading of the engine, not to exceed 30 minutes, after which time the non-startup emission limitations shall apply.

(4) The unit, including any associated air pollution control equipment, shall be operated at all times in a manner consistent with safety and good air pollution control practices for minimizing emissions. Determination of whether such operation and maintenance procedures are being used will be based on information available to the Department that may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the unit.

Maine DEP regulation 06-096 CMR Chapter 101 is currently undergoing revisions. It is our understanding that the startup work practice standards identified above will be incorporated into the new version of the regulation. Should the work practice standards in the new version of the regulation change, JAX will file an additional minor revision application to reflect the changes.

APPENDIX A: EMISSION CALCULATIONS

Ethylene Oxide Sterilization Unit

Sterilizer Make: 3M
Sterilizer Model: Steri-Vac™ Sterilizer GS8X
Abator Model: EO Abator 50AN

Table 1: Potential EtO Emissions Based on Continuous Operation

EtO per Cartridge:	170	[gm/batch]
	0.37	[lb/batch]
Minimum Batch Time[1]:	1	[hrs/batch]
Potential Operation:	8760	[hrs/yr]
Number of Units:	1	[-]
Potential Batches:	8760	[batches/yr]
EtO Usage Per Year:	3283	[lbs/yr]
Abator Control:	99.9%	[%]
EtO Emissions:	**3.3**	**[lbs/yr]**

[1]The minimum batch time is defined as the shortest programmable cycle in which the sterilizer utilizes one EtO cartridge. JAX operates the EtO unit on batch cycles times much longer than one hour per cartridge. The potential batches per year presented in Table 1 is much higher than the expected annual number of batches performed by JAX.

Table 2: Potential CO_2 Emissions Based on Continuous Operation

EtO Usage Per Year:	3283	[lbs/yr]
EtO Destruction Efficiency:	99.9%	[%]
EtO Destroyed Per Year:	3279.858	[lbs/yr]
Moles EtO Destroyed:	74.5	[lbmol]
Moles of CO_2 Produced:	148.9	[lbmol]
CO_2 Produced Per Year:	6553.8	[lbs/yr]
	3.28	[TPY]

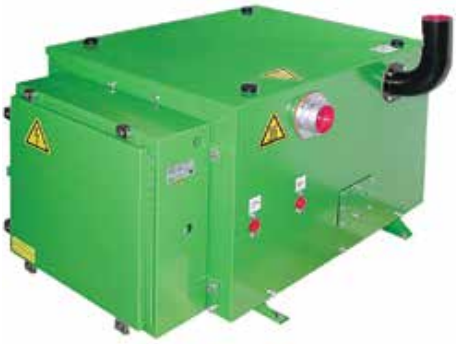
Table 3: Emissions Increase

Pollutant	Steri-Vac™ Sterilizer GS8X Emissions [TPY]
VOC	1.64E-03
HAP	1.64E-03
CO_2	3.28

APPENDIX B: EQUIPMENT MANUFACTURER'S SPECIFICATION SHEETS

Specifications

3M™ EO Abator



The 3M™ EO Abator is a highly effective device used to catalytically convert 100% ethylene oxide gas exhausted from the 3M™ Steri-Vac™ Sterilizer/Aerators GS and GSX Series to CO_2 and water vapor. At normal operating conditions, removal efficiency is 99.9+% (when EO is >100 ppm), virtually eliminating emissions to meet environmental requirements. The 3M EO Abator is designed exclusively for use with 3M™ Steri-Vac™ Sterilizer/Aerators GS and GSX Series.

	3M™ EO Abator	
Physical Dimensions		
Width	900 mm (36 in.)	
Height	800 mm (31.5 in.)	
Depth	1050 mm (41.5 in.)	
Weight	Operating: 155.6 kg (343 lbs) Shipping: 245.8kg (542lbs)	
Sound Levels	<85 dBA	
Electrical Power Requirements		
Frequency	50–60 Hz	
Installation/Over Voltage Category	Category II	
Distance from earth ground to Abator	<40 m (130 ft)	
Model	**Voltage**	**Current**
Model 50 AN (US/Canada)	220-240V Single Phase Volts AC	30 Amps
Model 50AE (Europe)	400V (±10%), Three Phase Volts AC	17 Amps
Model 50AJ (Japan)	200V (±10%), Three Phase Volts AC	28 Amps
Required Environmental Operating Conditions		
Altitude	≤ 2500 meters	
Relative Humidity	20 – 80 % (non-condensing)	
Operating Temperature	0–49°C	
Exhaust Temperature	Idle (Ready): 138°C (280°F) Normal: 238°C Maximum: 260°C	
Abator Operating Parameters		
Pollution Degree	2	
Heat Source	6 kW Electric Duct Heater	
Maximum Air Flow	1.4 NCMM (50 SCFM)	
Maximum EO Feed Rate	7.7 g/min (0.017 lbs/min)	
Required Service Access		
Service Footprint (H × W × D)	171.45 × 193.04 × 166.37 cm (67.5 × 76 × 65.5 in.)	
Top/above unit	900 mm (36 in.)	
Left and right sides	500 mm (20 in.)	
Front side	500 mm (20 in.)	
Back side	100 mm (4 in.)	

Requirements for Length and Diameter of Vent Line for EO inlet

Number of Sterilizers connected to Abator	Length <31 m (100 ft)	31 m (100 ft) ≤ length, 61 m (200 ft)	31 m (100 ft) ≤ length <61 m (200 ft)
1	2.5 cm (1.0 in.)		
2***	2.5 cm (1.0 in.)	3.8 cm (1.5 in.)	3.8 cm (1.5 in.)

***Note: The XL Series sterilizer **cannot** be combined with a GS/GSX Series sterilizer when connecting two sterilizers to one abator.

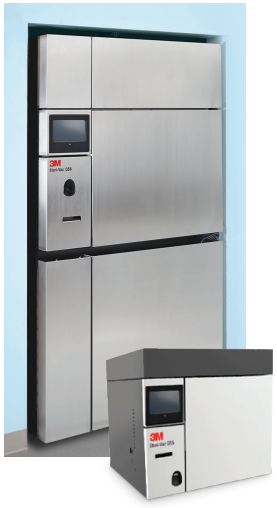
For more information, U.S. customers contact the
3M Health Care Service Group Helpline: 1-800-292-6298.

Outside of the U.S., contact your local 3M office. See www.3M.com for office locations.

Infection Prevention Division
3M Health Care
2510 Conway Avenue
St. Paul, MN 55144-1000 USA
800-228-3957
www.3M.com/infectionprevention

3M Science. Applied to Life.™

3M™ Steri-Vac™ Sterilizer/ Aerator GS Series



3M™ Steri-Vac™ Sterilizer/ Aerator GS Series is a 100% ethylene oxide sterilization system that is an effective low temperature sterilization method for medical devices and other applications. The GS Series sterilizers, Models GS5 and GS8 are designed for use in health care, and Models GS5X and GS8X for use in life science, medical device, contract sterilization, R&D laboratory applications, and other research and industrial applications for terminal sterilization. The GS Series sterilizers provide control and independent monitoring with state-of-the-art, compliant mechanical design.

For more information, contact your 3M Sales Representative or **3M Health Care Customer Helpline: 1-800-364-3577.**

Specifications

			Models GS5 and GS5X	Models GS8 and GS8X
Dimensions and Weight	Shipping Weight	Single Door	163 kg (359 lbs.)	387 kg (852 lbs.)
		Double Door	172 kg (379 lbs.)	400 kg (882 lbs.)
	Operational Weight	Single Door	131 kg (290 lbs.)	314 kg (692 lbs.)
		Double Door	141 kg (310 lbs.)	328 kg (722 lbs.)
	Exterior Dimensions H x W x D		70.9×76.2×95.0 cm (27.9×30.0×37.4 in.)	179.8×94.0×109.0 cm (70.8×37.0×42.9 in.)
Sterilization Chamber	Volume		136 L (4.8 ft³)	224 L (7.9 ft³)
	Dimensions H x W x D		38.0×43.0×83.0 cm (15.0×17.0×32.5 in.)	46.0×51.0×97.0 cm (18.0×20.0×38.0 in.)
	Load Basket Dimensions W x L x H	Lower Basket:	39.0×80.0×18.0 cm (15.5×31.5×7.0 in.)	34.0×95.0×20.0 cm (18.5×37.5×8.0 in.)
		Upper Basket:	39.0×80.0×18.0 cm (15.5×31.×7.0 in.)	47.0×47.0×20.0 cm (18.5×18.5×8.0 in.)
Sound	Sound Levels		< 85 dBA	
Electrical Power	Voltage Range		200–240 VAC	
	Frequency		50/60 Hz	
	Phase		Single	
	Current		15 amp dedicated circuit	
	Heat Load		5500 Btu/hr	6150 Btu/hr
	Internal Circuit Breaker		7 amp	12 amp
Environmental Operating Conditions	Altitude		2500 M (maximum)	
	Operating Temperature		15–35°C	
	Humidity		20–80% relative humidity (non-condensing)	
	Room Air Exchanges		10 per hour (minimum)	
	Minimum Room Size		30 m³ (1000 ft³)	
Compressed Air Specifications	Pressure		7.0 kg/cm² (100 psig) minimum to 10.5 kg/cm² (150 psig) maximum	
	Flow Rate		2.2 liters per second at 5.3 kg/cm² (4.7cubic feet per minute at 75 psig) per sterilizer, 100% duty cycle compressor	
	Quality		Clean air supply with a maximum allowable dirt particle size of 0.5 microns and free of oil	
	Moisture Content		Less than 10°C (50°F) dew point	
Required Service Access	Minimum distance from rear wall		10.2 cm (4 in.)	
	Minimum access on both sides and top		51 cm (20 in.)	
	Service Footprint H x W x D		70 × 76 × 89 cm (27½×30×35 in.)	179×94×109 cm (70½×37×43 in.)
Ethylene Oxide Storage Requirements	Cabinet		Approved flammable liquid storage cabinet	
	Venting		Vented to outside or to a non-recirculating, continuously operating, dedicated exhaust system	

Additional site planning information is available in the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series Site Planning & Installation Guide.

Available in Canada from:
3M Infection Prevention Solutions
3M Canada Company
P.O. Box 5757
London, Ontario N6A 4TI
Canada
1-800-364-3577
www.3M.ca/healthcare

3M Health Care
3M Center, Building 275-4E-01
Conway Avenue, St. Paul, MN
55144-1000 USA

APPENDIX C: ETO CARTRIDGE SAFETY DATA SHEET

Safety Data Sheet

Document Group:	10-3495-8	**Version Number:**	55.00
Issue Date:	02/19/14	**Supercedes Date:**	11/22/13

SECTION 1: Identification

1.1. Product identifier
STERI-GAS BRAND CARTRIDGES 4-60, 4-100, 4-134, and 8-170

Product Identification Numbers
70-2007-2768-6, 70-2007-4128-1, 70-2007-4129-9, 70-2007-4130-7, 70-2007-4132-3, 70-2007-4133-1, 70-2007-4134-9, 70-2007-4135-6, 70-2007-4136-4, 70-2007-4137-2, 70-2007-4138-0, 70-2007-4140-6, 70-2007-4142-2, 70-2007-7124-7, 70-2007-7125-4, 70-2007-8376-2, 70-2007-8377-0, 70-2007-8378-8, 70-2007-8379-6, 70-2007-8380-4, 70-2007-8381-2, 70-2007-8382-0, 70-2007-8383-8, 70-2007-8384-6, 70-2007-8385-3

1.2. Recommended use and restrictions on use

Recommended use
Gas to sterilize in a 3M Steri-Vac(TM) Ethylene Oxide Sterilizer

1.3. Supplier's details

MANUFACTURER:	3M
DIVISION:	Infection Prevention Division
ADDRESS:	3M Center, St. Paul, MN 55144-1000, USA
Telephone:	1-888-3M HELPS (1-888-364-3577)

1.4. Emergency telephone number
1-800-364-3577 or (651) 737-6501 (24 hours)

SECTION 2: Hazard identification

2.1. Hazard classification
Flammable Gas: Category 1.
Gas Under Pressure: Liquefied gas.
Acute Toxicity (inhalation): Category 3.
Serious Eye Damage/Irritation: Category 2A.
Skin Corrosion/Irritation: Category 2.
Reproductive Toxicity: Category 2.
Carcinogenicity: Category 1A.
Germ Cell Mutagenicity: Category 1B.
Specific Target Organ Toxicity (single exposure): Category 1.
Specific Target Organ Toxicity (central nervous system): Category 3.
Specific Target Organ Toxicity (repeated exposure): Category 1.

2.2. Label elements
Signal word
Danger

Symbols
Flame | Gas cylinder | Skull and crossbones | Exclamation mark | Health Hazard |

Pictograms

Hazard Statements
Extremely flammable gas.
Contains gas under pressure; may explode if heated.

Toxic if inhaled.
Causes serious eye irritation.
Causes skin irritation.
May cause drowsiness or dizziness.
Suspected of damaging fertility or the unborn child.
May cause cancer.
May cause genetic defects.

Causes damage to organs:
respiratory system |

Causes damage to organs through prolonged or repeated exposure:
nervous system |

kidney/urinary tract |
sensory organs |

Precautionary Statements

Prevention:
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Do not breathe dust/fume/gas/mist/vapors/spray.
Use only outdoors or in a well-ventilated area.
Wear protective gloves and eye/face protection.
Do not eat, drink or smoke when using this product.
Wash thoroughly after handling.

Response:
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
Continue rinsing.
If eye irritation persists: Get medical advice/attention.
IF ON SKIN: Wash with plenty of soap and water.
If skin irritation occurs: Get medical advice/attention.
Take off contaminated clothing and wash it before reuse.
IF exposed or concerned: Get medical advice/attention.

Call a POISON CENTER or doctor/physician.
Leaking gas fire: Do not extinguish, unless leak can be stopped safely.
Eliminate all ignition sources if safe to do so.

Storage:
Protect from sunlight. Store in a well-ventilated place.
Keep container tightly closed.
Store locked up.

Disposal:
Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

Notes to Physician:
Not applicable

2.3. Hazards not otherwise classified
May cause frostbite.

SECTION 3: Composition/information on ingredients

Ingredient	C.A.S. No.	% by Wt
ETHYLENE OXIDE	75-21-8	100

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation:
Remove person to fresh air. Get medical attention.

Skin Contact:
Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, get medical attention.

Eye Contact:
Immediately flush with large amounts of water for at least 15 minutes. Remove contact lenses if easy to do. Continue rinsing. Immediately get medical attention.

If Swallowed:
Rinse mouth. Do not induce vomiting. Get immediate medical attention.

4.2. Most important symptoms and effects, both acute and delayed
See Section 11.1. Information on toxicological effects.

4.3. Indication of any immediate medical attention and special treatment required
Not applicable

SECTION 5: Fire-fighting measures

5.1. Suitable extinguishing media
Refer to other precautionary advice in SDS section 5.

5.2. Special hazards arising from the substance or mixture
Closed containers exposed to heat from fire may build pressure and explode.

Hazardous Decomposition or By-Products

Substance	Condition
Carbon monoxide	During Combustion
Carbon dioxide	During Combustion

5.3. Special protective actions for fire-fighters
Leaking gas fire: Do not extinguish, unless leak can be stopped safely. Eliminate all ignition sources if safe to do so.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Evacuate area. Eliminate all ignition sources if safe to do so. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Ventilate the area with fresh air. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

6.2. Environmental precautions
Avoid release to the environment.

6.3. Methods and material for containment and cleaning up
If possible, seal leaking container. Place leaking containers in a well-ventilated area, preferably an operating exhaust hood, or if necessary outdoors on an impermeable surface until appropriate packaging for the leaking container or its contents is available. Dispose of collected material as soon as possible.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
For industrial or professional use only. Do not use in a confined area with minimal air exchange. Do not handle until all safety precautions have been read and understood. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Take precautionary measures against static discharge. Do not breathe dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Avoid release to the environment. Eliminate all ignition sources if safe to do so. Avoid contact with oxidizing agents (eg. chlorine, chromic acid etc.) Use personal protective equipment (gloves, respirators, etc.) as required. Recommendations for storing Steri-Gas cartridges are stringent. Check your local fire protection codes for additional requirements. Keep all sources of ignition such as matches, lighted cigarettes, sparks and static discharge away from the sterilzer and cartridges. Store cartridges in an upright position. Keep only one day's requirement or a maximum of twelve(12) cartridges (one box) in the immediate sterilizer area. This area needs to have at least ten air changes per hour. Additional Steri-Gas cartridges should be stored in an approved flammable liquid storage cabinet vented to the outside atmosphere, or in an area suitable for storage of flammable liquids appropriately vented to the outside atmosphere, or into a non-recirculating, continuously operating, dedicated exhaust system.

7.2. Conditions for safe storage including any incompatibilities
Store in a well-ventilated place. Keep container tightly closed. Protect from sunlight. Store away from heat. Store away from acids. Store away from oxidizing agents. Store away from areas where product may come into contact with food or pharmaceuticals.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Ingredient	C.A.S. No.	Agency	Limit type	Additional Comments

ETHYLENE OXIDE	75-21-8	Manufacturer determined	STEL:5 ppm	
ETHYLENE OXIDE	75-21-8	Amer Conf of Gov. Indust. Hyg.	TWA:1 ppm	
ETHYLENE OXIDE	75-21-8	US Dept of Labor - OSHA	TWA:1 ppm;STEL:5 ppm	29 CFR 1910.1047

Amer Conf of Gov. Indust. Hyg. : American Conference of Governmental Industrial Hygienists
American Indust. Hygiene Assoc : American Industrial Hygiene Association
Chemical Manufacturer Rec Guid : Chemical Manufacturer's Recommended Guidelines
US Dept of Labor - OSHA : United States Department of Labor - Occupational Safety and Health Administration
TWA: Time-Weighted-Average
STEL: Short Term Exposure Limit
CEIL: Ceiling

8.2. Exposure controls

8.2.1. Engineering controls
Use general dilution ventilation and/or local exhaust ventilation to control airborne exposures to below relevant Exposure Limits and/or control dust/fume/gas/mist/vapors/spray. If ventilation is not adequate, use respiratory protection equipment.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:
Indirect Vented Goggles

Skin/hand protection
Select and use gloves and/or protective clothing approved to relevant local standards to prevent skin contact based on the results of an exposure assessment. Selection should be based on use factors such as exposure levels, concentration of the substance or mixture, frequency and duration, physical challenges such as temperature extremes, and other use conditions. Consult with your glove and/or protective clothing manufacturer for selection of appropriate compatible gloves/protective clothing.
Gloves made from the following material(s) are recommended: Butyl Rubber

Respiratory protection

An exposure assessment may be needed to decide if a respirator is required. If a respirator is needed, use respirators as part of a full respiratory protection program. Based on the results of the exposure assessment, select from the following respirator type(s) to reduce inhalation exposure:
Full facepiece supplied-air respirator

For questions about suitability for a specific application, consult with your respirator manufacturer.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

General Physical Form:	Gas
Specific Physical Form:	Compressed Gas
Odor, Color, Grade:	COLORLESS GAS IN NORMAL USE. SWEET ODOR AT 500-750 PPM
Odor threshold	*No Data Available*
pH	7
Melting point	*Not Applicable*

Boiling Point	51 ºF
Flash Point	-4 ºF [*Test Method:* Tagliabue Closed Cup]
Evaporation rate	*Not Applicable*
Flammability (solid, gas)	Flammable Gas: Category 1.
Flammable Limits(LEL)	3 % volume
Flammable Limits(UEL)	100 % volume
Vapor Pressure	1094 mmHg [@ 20 ºC]
Vapor Density	1.5 [*Ref Std:* AIR=1]
Density	*Not Applicable*
Specific Gravity	0.87 [*Ref Std:* WATER=1] [*Details:* CONDITIONS: @ 20/20 C]
Solubility in Water	Complete
Solubility- non-water	*No Data Available*
Partition coefficient: n-octanol/ water	*No Data Available*
Autoignition temperature	804 ºF [*Details:* CONDITIONS: Burns in the absence of air]
Decomposition temperature	*Not Applicable*
Viscosity	*Not Applicable*
Volatile Organic Compounds	100 %
Percent volatile	100 %
VOC Less H2O & Exempt Solvents	100 %

SECTION 10: Stability and reactivity

10.1. Reactivity
This material is considered to be non reactive under normal use conditions.

10.2. Chemical stability
Stable.

10.3. Possibility of hazardous reactions
Hazardous polymerization may occur.

10.4. Conditions to avoid
Heat

10.5. Incompatible materials
None known.

10.6. Hazardous decomposition products

Substance	**Condition**
None known.	

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labeling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

11.1. Information on Toxicological effects

Signs and Symptoms of Exposure

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation:
Toxic if inhaled.
Respiratory Tract Irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

May cause target organ effects after inhalation.

Skin Contact:
Frostbite: Signs/symptoms may include intense pain, discoloration of skin, and tissue destruction.

Skin Irritation: Signs/symptoms may include localized redness, swelling, itching, dryness, cracking, blistering, and pain.

Eye Contact:
Frostbite: Signs/symptoms may include intense pain, clouding of the cornea, redness, swelling, and blindness.

Severe Eye Irritation: Signs/symptoms may include significant redness, swelling, pain, tearing, cloudy appearance of the cornea, and impaired vision.

Ingestion:
Gastrointestinal Irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

Target Organ Effects:

Single exposure may cause:
Central Nervous System (CNS) Depression: Signs/symptoms may include headache, dizziness, drowsiness, incoordination, nausea, slowed reaction time, slurred speech, giddiness, and unconsciousness.

Respiratory Effects: Signs/symptoms may include cough, shortness of breath, chest tightness, wheezing, increased heart rate, bluish colored skin (cyanosis), sputum production, changes in lung function tests, and/or respiratory failure.

Prolonged or repeated exposure may cause:
Ocular Effects: Signs/symptoms may include blurred or significantly impaired vision.

Peripheral Neuropathy: Signs/symptoms may include tingling or numbness of the extremities, incoordination, weakness of the hands and feet, tremors and muscle atrophy.

Kidney/Bladder Effects: Signs/symptoms may include changes in urine production, abdominal or lower back pain, increased protein in urine, increased blood urea nitrogen (BUN), blood in urine, and painful urination.

Reproductive/Developmental Toxicity:
Contains a chemical or chemicals which can cause birth defects or other reproductive harm.

Genotoxicity:
Genotoxicity and Mutagenicity: May interact with genetic material and possibly alter gene expression.

Carcinogenicity:
Contains a chemical or chemicals which can cause cancer.

Ingredient	C.A.S. No.	Class Description	Regulation
ETHYLENE OXIDE	75-21-8	Cancer hazard	OSHA Carcinogens
ETHYLENE OXIDE	75-21-8	Grp. 1: Carcinogenic to humans	International Agency for Research on Cancer
ETHYLENE OXIDE	75-21-8	Known human carcinogen	National Toxicology Program Carcinogens

Toxicological Data
If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
Overall product	Inhalation-Gas(4 hr)		No data available; calculated ATE 973.3 ppm
ETHYLENE OXIDE	Inhalation-Gas (4 hours)	Rat	LC50 1,460 ppm
ETHYLENE OXIDE	Ingestion	Rat	LD50 330 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
ETHYLENE OXIDE	Rabbit	Irritant

Serious Eye Damage/Irritation

Name	Species	Value
ETHYLENE OXIDE	official classification	Severe irritant

Skin Sensitization

Name	Species	Value
ETHYLENE OXIDE	Human and animal	Some positive data exist, but the data are not sufficient for classification

Respiratory Sensitization

Name	Species	Value
ETHYLENE OXIDE	Human	Some positive data exist, but the data are not sufficient for classification

Germ Cell Mutagenicity

Name	Route	Value
ETHYLENE OXIDE	In vivo	Mutagenic

Carcinogenicity

Name	Route	Species	Value
ETHYLENE OXIDE	Inhalation	Multiple animal species	Carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test Result	Exposure Duration
ETHYLENE OXIDE	Inhalation	Some positive developmental data exist, but the data are not sufficient for classification	Rat	NOAEL 33 ppm	during organogenesis
ETHYLENE OXIDE	Inhalation	Toxic to female reproduction	Rat	NOAEL 33 ppm	1 generation
ETHYLENE OXIDE	Inhalation	Toxic to male reproduction	Monkey	LOAEL 50 ppm	2 years

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration
ETHYLENE OXIDE	Inhalation	respiratory system	Causes damage to organs	Human and animal	NOAEL Not available	
ETHYLENE OXIDE	Inhalation	central nervous system depression	May cause drowsiness or dizziness	Human	NOAEL Not available	
ETHYLENE OXIDE	Inhalation	respiratory irritation	May cause respiratory irritation		NOAEL Not available	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration
ETHYLENE OXIDE	Inhalation	peripheral nervous system	Causes damage to organs through prolonged or repeated exposure	Human and animal	NOAEL Not available	
ETHYLENE OXIDE	Inhalation	kidney and/or bladder	May cause damage to organs though prolonged or repeated exposure	Mouse	LOAEL 100 ppm	14 weeks
ETHYLENE OXIDE	Inhalation	eyes	May cause damage to organs though prolonged or repeated exposure	Human and animal	NOAEL Not available	
ETHYLENE OXIDE	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification	Mouse	LOAEL 200 ppm	14 weeks
ETHYLENE OXIDE	Inhalation	endocrine system	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 100 ppm	2 years
ETHYLENE OXIDE	Inhalation	liver	Some positive data exist, but the data are not sufficient for classification	Multiple animal species	NOAEL 841 ppm	not available
ETHYLENE OXIDE	Inhalation	hematopoietic system	Some positive data exist, but the data are not sufficient for classification	Mouse	NOAEL 250 ppm	10 weeks
ETHYLENE OXIDE	Inhalation	immune system	Some positive data exist, but the data are not sufficient for classification	Mouse	LOAEL 200 ppm	14 weeks
ETHYLENE OXIDE	Inhalation	heart	All data are negative	Monkey	NOAEL 100 ppm	2 years

Aspiration Hazard

Name	Value

Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.

SECTION 12: Ecological information

Ecotoxicological information

Test Organism	Test Type	Result
Water flea, Daphnia magna	48 hours	137 mg/l
Fathead Minnow, Pimephales promelas	96 hours	84 mg/l
Goldfish, Carassius auratus	24 hours	90 mg/l

Please contact the address or phone number listed on the first page of the SDS for additional ecotoxicological information on this material and/or its components.

Chemical fate information

Test Type	Result	Protocol
28 days Biological Oxygen Demand	107	
Log of Octanol/H2O part. coeff	-0.3	Est: Octanol-water part. coeff

Please contact the address or phone number listed on the first page of the SDS for additional chemical fate information on this material and/or its components.

SECTION 13: Disposal considerations

13.1. Disposal methods
Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Dispose of waste product in a permitted industrial waste facility. The facility should be equipped to handle gaseous waste. Empty drums/barrels/containers used for transporting and handling hazardous chemicals (chemical substances/mixtures/preparations classified as Hazardous as per applicable regulations) shall be considered, stored, treated & disposed of as hazardous wastes unless otherwise defined by applicable waste regulations. Consult with the respective regulating authorities to determine the available treatment and disposal facilities.

EPA Hazardous Waste Number (RCRA): D001 (Ignitable)

SECTION 14: Transport Information

For Transport Information, please visit **http://3M.com/Transportinfo** or call 1-800-364-3577 or 651-737-6501.

SECTION 15: Regulatory information

15.1. US Federal Regulations
Contact 3M for more information.

311/312 Hazard Categories:

Fire Hazard - Yes Pressure Hazard - Yes Reactivity Hazard - Yes Immediate Hazard - Yes Delayed Hazard - Yes

Section 313 Toxic Chemicals subject to the reporting requirements of that section and 40 CFR part 372 (EPCRA):

Ingredient	C.A.S. No	% by Wt
ETHYLENE OXIDE	75-21-8	100

This chemical is a pesticide product registered by the United States Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including directions for use.
Do not swallow.
Causes skin and eye burns
May be fatal if inhaled in high concentrations

15.2. State Regulations
Contact 3M for more information.

15.3. Chemical Inventories
Contact 3M for more information.

15.4. International Regulations
Contact 3M for more information.

This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.

SECTION 16: Other information

NFPA Hazard Classification
Health: 3 **Flammability:** 4 **Instability:** 3 **Special Hazards:** None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

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APPENDIX D: RESPONSIBLE OFFICIAL SIGNATURE PAGE

Section K:SIGNATORY REQUIREMENT

Each application submitted to the Department must include the following certification signed by a Responsible Official*:

"I certify under penalty of law that, based on information and belief formed after reasonable inquiry, I believe the information included in the attached document is true, complete, and accurate."

_____ _____08/27/2018_____
Responsible Official Signature Date

____David A. Kuchta_____ Maintenance and Utility Plant Manger
Responsible Official (Printed or Typed) Title

* A Responsible Official is defined by MEDEP Rule, Chapter 100 as:

A. For a corporation: a president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation, or a duly authorized representative of such person if the representative is responsible for the overall operation of one or more manufacturing, production, or operating facilities applying for or subject to a permit and either:

(1) The facilities employ more than 250 persons or have gross annual sales or expenditures exceeding $25 million (in second quarter 1980 dollars); or

(2) The delegation of authority to such representatives is approved in advance by the permitting authority;

B. For a partnership or sole proprietorship: a general partner or the proprietor, respectively;

C. For a municipality, State, Federal, or other public agency: Either a principal executive officer or ranking elected official. For the purposes of this part, a principal executive officer of a Federal agency includes the chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency (e.g., a Regional Administrator of EPA).

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